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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/283,318	03/31/1999	JACK V. SMITH		9827

7590 10/29/2004

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/283,318	SMITH, JACK V.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to paper filed April 13, 2004.

Claims 23- 29 are under consideration.

Rejections Maintained

Claim Rejections - 35 USC § 112

Claims 23- 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims were rejected because it appeared that the test strip would always give a positive result and it was not clear what "means" intended.

Does increase in color indicate more antibodies? This needs to be indicated in the claims. Furthermore, it is not clear how the claimed assay cannot be ELISA if it uses enzyme and detection substrate.

Applicant appears to argue the 112 first and second paragraph rejections together.

On page 6, top, Applicant explains the color reaction.

Applicant's arguments have been fully considered and found persuasive in part.

Applicant has indicated what color indicates the presence of antibody.

Applicant has not indicated the color obtained in the claims. The claims are drawn to a method and this is what indicates what the result is and the result is needed

to complete the claims. Without this indication the method is not complete and the claims do not clearly differentiate themselves from an ELISA.

Applicant has not amended the claims or explained the term "means" as previously rejected.

Claims 23- 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a labeled antigen used to detect antibodies against HIV.

Applicant appears to argue the 112 first and second paragraph rejections together. It appears that page 5, page 6 lower half, and pages 7- 9 are directed toward the 112, first paragraph rejection.

Applicant argues that his daughter is able to make solutions, explains the amounts used for detection, making a color chart, and a table on page 8 of the response to overcome the enablement and guidance issues.

Applicant's arguments have been fully considered and not found persuasive.

Applicant argument that his daughter can make the solutions is not commensurate with the claims or the rejection. The claims are drawn to a method of detecting HIV antibodies not of making solutions.

The showing of portions of "links" on the bottom of page 6 does not provide convincing evidence for color charts or quantities of detection. If Applicant wants these documents considered they must be submitted listed on a PTO form 1449 and full copies provided.

The results shown by Applicant on page 8 of the response do not shown the conditions used in making the test (how the strips were made and how they were used and does not show quantitation of detected antibodies. An affidavit, as offered by Applicant, that shows relevant portions of lab notebooks and results that show the methods used would be considered. A table labeled "Present Art" with no reference to methods employed is not persuasive.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fuerst *et al.* (US6214970B1) and van de Perre *et al.* (J Clinical Microbio 1988 Vol 26, pages 552-556).

The invention is drawn to a method to make a test means to detect antibody using an enzyme- substrate indicator.

Fuerst *et al.* teach an assay to detect antibodies in blood that is not ELISA or HPLC comprising an absorbent carrier matrix (including a dip stick) with two solutions 1) HIV antigen conjugated to enzyme and buffer and 2) indicator substrate, and detecting antibodies by change in color produced (column 27, line 42 to column 28, line 9).

Fuerst *et al.* does not teach HIV antibody detection or dried impregnated test means.

van de Perre *et al.* teach that there is a need to detect anti-HIV antibodies and that simple and inexpensive tests are required as alternatives to more expensive tests and that the tests should be performed easily in the field (page 552, first paragraph and the discussion section).

One of ordinary skill in the art at the time of invention would have known from the prior art teachings of dipsticks that they can be prepared and dried for ease of use. One of ordinary skill in the art at the time of invention would have been motivated to use the assay of Fuerst *et al.* to detect HIV antibodies because there is a need to detect HIV antibodies and the test of Fuerst *et al.* is simple and easy to perform. Both references teach dectection of antibodies and one of ordinary skill in the art would have known that the test of Fuerst *et al.* could be used to detect other antibodies.

One of ordinary skill in the art at the time of invention would have known that Fuerst *et al.* teach the invention essentially as claimed. The choice of antibody to detect

does not add patentable weight to the method nor does the choice of enzyme-indicator substrates.

One of ordinary skill in the art at the time of invention would have known that dipsticks are meant to be tests that are self contained and in ready to use form. One of ordinary skill would have been able to determine how to impregnate and dry the strips for use as test means in the form of a dipstick.

Thus, it would have been *prima facie* obvious at the time of invention to modify the assay of Fuerst *et al.* to detect HIV antibodies with the expectation of success because the method of detecting antibodies of Fuerst *et al.* is known in the art to work.

Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuerst *et al.* (US6214970B1) and van de Perre *et al.* as discussed above and Harlow and Lane (Antibodies A Laboratory Manual).

The invention is drawn to a method to make a test means to detect antibody using an enzyme- substrate indicator using a wide range of enzyme- substrate indicators.

As discussed above, Fuerst *et al.* and van de Perre *et al.* teach a method of detecting HIV antibodies.

Fuerst *et al.* and van de Perre *et al.* do not teach all the enzymes and substrates.

Harlow and Lane teach that certain enzymes can be used for dipstick type (solid phase) assays including horseradish peroxidase and alkaline phosphatase (pages 592-598).

One of ordinary skill in the art at the time of invention would have known from the prior art teachings that there are many enzyme-substrate combinations known used in ELISA and western blots that can be used in this method. The substitution of equivalent parts and optimization are routine in the art.

One of ordinary skill in the art at the time of invention would have known that Fuerst *et al.* teach the invention essentially as claimed. The choice of antibody to detect does not add patentable weight to the method nor does the choice of enzyme-indicator substrates.

Thus, it would have been *prima facie* obvious at the time of invention to modify the assay of Fuerst *et al.* to detect HIV antibodies using a variety of enzyme-substrate combinations as known in the art with the expectation of success because the method of detecting antibodies using enzyme-substrate combinations is known in the art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
October 28, 2004

ALI R. SALIMI
PRIMARY EXAMINER